Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Benefit of Oral Platanus and Rosemary extract on clinical, physiological and biological improvement of resistant asthma, a double blind randomized placebo controlled active comparator study on asthmatic resistant to traditional treatment.

Protocol summary

Summary

Objectives: Platanus and rosemary extract were routinely used in Iranian traditional medicine for asthma. They proved to be safe and without complication. The objective of this study was to determine their effect on treatment of resistant asthma. Design: Prospective randomized controlled clinical trial (active comparator study) Setting and conduct: A pulmonary subspecialty clinic Participants including major eligibility criteria: Thirty asthmatic subjects whom at least three drugs for treatment for asthma was not effective to control asthma will be enrolled in this clinical trial. Smokers and subjects suffering from other underlying diseases such as infection will be excluded from study. The subjects will be randomly divided into two groups which for one of them platanus extract plus placebo will be administered and the other will be consumed rosemary extract plus placebo. Intervention: After randomization eligible subjects will receive one plant extract (Platanus or Rosemary). Independent pharmacists dispensed either Platanus or Rosemary according to a computer generated randomization list. Each extract plus placebo will be consumed for one month, after this period they will be evaluated for main parameters and they will receive placebo for wash out. After one month, they will receive another extract plus placebo and again they will experience one month wash out period. At the last month, they will receive both drugs. Main outcome measures (variables): pulmonary clinical findings, spirometry, Exhaled Nitric Oxide (FENO) and asthma control test (ACT).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107312695N2**
Registration date: **2013-05-13, 1392/02/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-05-13, 1392/02/23

Registrant information

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Name of organization / entity

Islamic Azad University- Mashhad branch

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research- Islamic Azad University- Mashhad Branch

Expected recruitment start date

2013-03-06, 1391/12/16

Expected recruitment end date

2014-08-06, 1393/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Benefit of Oral Platanus and Rosemary extract on clinical, physiological and biological improvement of resistant asthma, a double blind randomized placebo controlled active comparator study on asthmatic resistant to traditional treatment.

Public title
Benefit of platanus and Rosemary extract on treatment of resistant asthma

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: 1- Resistant asthma to Inhaled corticosteroid, long acting beta 2 agonist, antileukotrien and theophyllin Exclusion criteria: 1- Respiratory infection 2- Fair Treatment with controller drugs 3- Not cooperative with project 4- congestive heart failure 5- Gastroesophageal reflux 6- Rhinosinusitis, 7- pregnancy 8- smoking 9- non asthmatic other lung disease and non pulmonary disease

Age
From **12 years** old to **91 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Crossover

Other design features
All recruited asthmatic subjects will randomly divided to two groups of herbal extract by computer generated randomization list. Both groups contain one true herbal drug (Rosemary or Platanus) and one placebo. The physician and pharmacist are blind to the exact herbal drug which the subject will be started with (Rosemary or Platanus). The Platanus, Rosemary and their placebos were in bottle form and identical in appearance. They were prepacked in bottles and consecutively numbered for each patient according to the randomization schedule which is not introduced to the physician and pharmacist.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethical committee of Medical school Islamic Azad University- Mashhad branch

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Shahin Far Building- Sarab Street- Azadi street

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Postal code
9178673799

Approval date
2011-04-08, 1390/01/19

Ethics committee reference number
A34-18

Health conditions studied

1

Description of health condition studied
Asthma

ICD-10 code
J459

ICD-10 code description
Asthma, unspecified

Primary outcomes

1

Description
FEV1

Timepoint
before treatment and one month after treatment

Method of measurement
spirometry superspiro, Micromedical company, England

2

Description
Exhaled Nitric oxide (FENO)

Timepoint
before treatment and one month after treatment

Method of measurement
Chemiluminescence instrument, No Breath, Bedfont company, England

3

Description
ACT Questionnaire

Timepoint
before treatment and one month after treatment

Method of measurement
Validated Asthma control test Questionnaire

Secondary outcomes

1

Description
IL-17
Timepoint
Before treatment and One month after treatment
Method of measurement
ELIZA- Qiagen company Tehran Iran

2

Description
INF- Gamma
Timepoint
Before treatment and One month after treatment
Method of measurement
ELIZA- Qiagen company Tehran Iran

Intervention groups

1

Description
Starting the trial: As mentioned above all symptomatic asthmatic subjects whom were resistant to treatment with inhaled corticosteroids, Salmetrol, Montelukast and theophilline will be entered in this study. The subjects will continue their previous drugs after that they will be randomly divided in two groups to consume two new herbal drugs. One group will receive platanus extract and placebo in addition to previous drugs and second group will receive Rosemary extract and placebo. Rosemary and Platanus extract has produced by Birjand herbal company and served as liquid which will be drunk (50 CC three times a day). After one month the outcome variables will be evaluated. Evaluations consist of clinical evaluation as like as symptoms (cough and dyspnea) and sign (wheeze) and clinical improvement of asthma by validated ACT (Asthma control test) questionnaire; and paraclinical tests such as spirometry (Superspiro, Micromedical instruments, England) and FENO (No Breath, Bedfont Medical instruments, England). Subjects whom showed complete improving or side effects of extract will be exited from study. Then both groups will receive placebo with similar shape to previous drugs for one month in order to wash out previous drugs.
Category
Treatment - Drugs

2

Description
Second phase: Subjects will be evaluated for primary outcomes. Evaluations consist of clinical evaluation as like as symptoms (cough and dyspnea) and sign (wheeze) and clinical improvement of asthma by validated ACT (Asthma control test) questionnaire; and paraclinical tests such as spirometry (Superspiro, Micromedical instruments, England) and FENO (No Breath, Bedfont Medical instruments, England). Subjects whom showed complete improving or side effects of extract will be exited from study. At the third month the groups will be changed and they will use other extract. At the beginning of fourth month primary outcomes will be evaluated as mentioned above and then both groups will receive placebo again for wash out.
Category
Treatment - Drugs

3

Description
Third (last) phase: In the last month (fifth month) both groups will receive both extracts and trial will be finished with evaluation of outcome parameters for last time. Outcome parameters will be evaluated before and after of this phase. Evaluations consist of clinical evaluation as like as symptoms (cough and dyspnea) and sign (wheeze) and clinical improvement of asthma by validated ACT (Asthma control test) questionnaire; and paraclinical tests such as spirometry (Superspiro, Micromedical instruments, England) and FENO (No Breath, Bedfont Medical instruments, England).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Medical school Islamic Azad University- Mashhad branch
Full name of responsible person
Mojtaba Meshkat
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Shahin Far building, Sarab street, Azadi Avenue
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Islamic Azad University- Mashhad Branch
Full name of responsible person
Mojtaba Meshkat
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Islamic Azad University- Mashhad Branch
Proportion provided by this source
100

Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty